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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/643,623	SZAMOSI ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *15-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/10/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and Applicant's Arguments/Remarks, all filed 11/09/06 is acknowledged.

Applicant's election with traverse of Group I (claims 1-14) in the reply filed on 11/09/06 is acknowledged. The traversal is on the ground(s) that "All three Groups are related to fast-dissolving tablets and are closely related that a search and examination of the entire application can be made without serious burden on the Patent Office". This is not found persuasive because Groups I-III are distinct each from the other. Group II (claims 15-29) is distinct from Group I because Group II does not require the claimed percentage of low melting point compound and hardness values as do the Group I claims. Group III (claims 30-31) is distinct from Group I in that Group III does not require the inclusion of an active ingredient, whereas Group I requires it. Additionally, it is noted that the Group I hardness value range (about 2.0 or lower) claimed is different than that claimed in Group III (about 1 to about 2 kP or lower). Thus, the different groups would entail different issues with regards to patentability and enablement. The groups would require different searches in both patent- and non-patent databases and there is no expectation that the search for the different groups would be coextensive in scope. Thus, this creates a serious burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-31 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11/09/06.

Claims 1-31 are pending in this action. Claims 15-31 have been withdrawn (see above). Claims 1-14 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4 recites the limitation "*a hardness of about 2.0 or lower*". The claim is indefinite because it is unclear as to the unit of measurement being applied with regards to hardness of the tablet. The claim simply recites "2.0 or lower". No specific unit of measurement has been recited.

Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wehling *et al.* (U.S. Patent No. 5,178,878).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Wehling *et al.* ('878) disclose an effervescent dosage form in the form of a rapidly disintegrating tablet, whereby the tablet comprises a pharmaceutical active ingredient (col. 3, lines 45-58); (col. 4, lines 56-62); lubricants such as polyethylene glycol, hydrogenated and partially hydrogenated vegetable oils, animal fats, polyoxyethylene monostearate, light mineral oils and the like in amounts of up to 1.5 wt.% (col. 9, lines 8-20); and water soluble excipients such as saccharides, sugars, invert sugars and the like in amounts of up to 60 wt. % (col. 7, lines 35-51 and Example I). Sweeteners can be added in amounts of up to about 20 wt. %. Suitable sweeteners include aspartame (Table II – col. 13). Suitable excipients disclosed include mannitol (Tables I & II). Additional polymers include waxes (col. 11, line 50). The tablet has a hardness of about 1.5 kilo pounds (col. 10 lines 30-42).

Additional adjuvants disclosed include flavors, diluents, colors, binders, fillers, compaction vehicles and non-effervescent disintegrants (col. 7, lines 29-34).

The claims are anticipated by Wehling *et al.*

Claims 1, 4, 5, 7-9 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Mizumoto *et al.* (U.S. Patent No. 5,576,014).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Mizumoto *et al.* ('014) disclose intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

The claims are anticipated by Mizumoto *et al.*

Claims 1, 4, 5, 7-9 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Shimizu *et al.* (U.S. Patent No. 6,299,904 B1).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Shimizu *et al.* ('904) disclose a solid preparation, which is a tablet, having fast disintegration that comprises (i) a pharmaceutically active ingredient; (ii) one or more water-soluble sugar alcohols selected from the group consisting of sorbitol, maltitol, reduced starch saccharide, xylitol, reduced palatinose and erythritol and (iii) low-substituted hydroxypropycellulose (see Abstract); (col. 1, lines 8-57); (Claims 1 & 6). Two or more water-soluble sugar alcohols can be used as a mixture in a given ratio (col. 4, line 66 – col. 5, line 2).

Lubricants are disclosed in the composition and include: sucrose fatty acid ester, polyethylene glycol, talc, stearic acid, etc. Polyethylene glycol can be used in an amount of 0.01 to 10 weight parts (col. 6, lines 26-34).

Additives are disclosed in the composition and include: artificial sweeteners such as aspartame, flavorants, lubricants, colorants, stabilizers, disintegrators, etc. (col. 5, line 59 – col. 6, line 25).

The tablets have a hardness of about 2 to about 20 kg (col. 8, lines 5-8).

The claims are anticipated by Shimizu *et al.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wehling *et al.* (U.S. Pat. No. 5,178,878) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Wehling *et al.* ('878), as discussed above, teach an effervescent dosage form in the form of a rapidly disintegrating tablet, whereby the tablet comprises a pharmaceutical active ingredient (col. 3, lines 45-58); (col. 4, lines 56-62); lubricants such as polyethylene glycol, hydrogenated and partially hydrogenated vegetable oils, animal fats, polyoxyethylene monostearate, light mineral oils and the like in amounts of up to 1.5 wt.% (col. 9, lines 8-20); and water soluble excipients such as saccharides, sugars, invert sugars and the like in amounts of up to 60 wt. % (col. 7, lines 35-51 and Example I). Sweeteners can be added in amounts of up to about 20 wt. %. Suitable sweeteners include aspartame (Table II – col. 13). Suitable excipients disclosed include mannitol (Tables I & II). Additional polymers include waxes (col. 11, line 50). The tablet has a hardness of about 1.5 kilo pounds (col. 10 lines 30-42).

Additional adjuvants disclosed include flavors, diluents, colors, binders, fillers, compaction vehicles and non-effervescent disintegrants (col. 7, lines 29-34).

Wehling *et al.* do not teach a mixture comprising a low melting point monoglyceride, diglyceride and triglyceride and do not teach selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific mono-, di- and triglyceride mixtures as well as the specific vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Wehling *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an improved, highly effective and palatable tablet for drug delivery.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mizumoto *et al.* (U.S. Pat. No. 5,576,014) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Mizumoto *et al.* ('014), as discussed above, teach an intrabuccally dissolving compressed moldings in the form of a tablet that show quick disintegration and dissolution and having an adequate hardness of preferably 1.0 kg or more (see Abstract); (col. 4, lines 35-62); (col. 11, lines 23-40).

The tablets comprise suitable saccharides that include lactose, mannitol, glucose, sucrose, xylitol, maltose, sorbitol and the like. These saccharides may be used alone or as a mixture of two or more (col. 6, lines 37-46) and (Examples). The saccharides may be added in amounts of from 2 to 20% by weight (col. 14, line 6). The tablets also comprise any suitable active ingredient (col. 7, line 50 – col. 10, line 2).

Lubricants are included in the composition and include sucrose fatty acid esters, polyethylene glycol, talc, stearic acid and the like. These may be used alone or as a mixture of two or more (col. 13, lines 50-65).

Additive agents can be added and include disintegrating agents, binding agents, souring agents, artificial sweeteners such as aspartame, perfumes, lubricants, coloring agents and the like (col. 13, lines 32-49).

While Mizumoto *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Mizumoto *et al.* do not teach a mixture comprising a low melting point monoglyceride, diglyceride and triglyceride and do not teach selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific mono-, di- and triglyceride mixtures as well as the specific

vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Mizumoto *et al.* One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an effective drug delivery tablet.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Korab (U.S. Pat. No. 4,704,269) in view of Mauger *et al.* (U.S. Pat. No. 5,728,403).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Korab ('269) teaches a water soluble effervescent antacid, analgesic powder and tablet formulations comprising ingredients such as maltodextrin, fructose, sucrose, lactose, dextrose, sorbitol, and the like in amounts of about 15% to about 25%; lubricants such as polyethylene glycol, lubritab or other hydrogenated vegetable or unsaturated oils and the like. The presence of lubricants aids in the tablet-making process (see Abstract); (col. 4, line 28); (col. 5, lines 20-68). Lubricants are added in amounts of from about 1% to about 4% (Claim 23). Sweeteners are

included in the composition and include aspartame (col. 5, line 31). The tablets have a hardness of 5-10 kg (Example II – col. 7).

While Korab does not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Korab teaches hydrogenated vegetable or unsaturated oils can be included in the composition (col. 5, lines 50-53). Korab does not teach a mixture comprising a low melting point monoglyceride, diglyceride and triglyceride and do not teach selective hydrogenated oils such as palm kern oil or hydrogenated cottonseed oil.

Mauger *et al.* ('403) teach a pharmaceutical composition for oral administration comprising mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils. Specific mixtures taught include Cotomar®, Wecobee FS®, Witepsol E7S® and Massa Estariorm A®, which consists of a mixture of triglycerides, diglycerides and monoglycerides of saturated fatty acids. The (tri)glycerides aid in

masking the taste of orally administered drugs (col.1, lines 56-60) and also cause the composition to melt at body temperature (see col. 2, lines 39-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the specific mono-, di- and triglyceride mixtures as well as the specific vegetable oils such as cottonseed and palm kern oils as taught by Mauger *et al.* within the tablet compositions of Korab. One of ordinary skill in the art would be motivated to do so with a reasonable expectation of success because Mauger *et al.* teach a pharmaceutical composition that comprises mixtures of monoglycerides, diglyercides and triglycerides derived from vegetable oils such as palm kernel oil and cottonseed oils and teach that the glycerides aid in masking taste of drugs and enable the composition to melt at body temperature. The expected result would be an enhanced tablet for the administration of active agents.

Claims 1-9 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino *et al.* (U.S. Pat. No. 5,501,861).

The instant invention is drawn to a tablet comprising a low melting point compound that melts or softens at or below 37°C, a water soluble excipient and an active ingredient, wherein the low melting point compound comprises from about 0.01% to about 2.5% (wt/wt) of the tablet, and wherein the tablet has a hardness of about 2.0 or lower.

Makino *et al.* ('861) teach a fast dissolving tablet comprising a pharmacologically active ingredient; carbohydrate including starch sugars, sugar alcohols, tetroses and so on, in amounts of 10 to 90% by weight; and lubricants that include sucrose fatty acid esters, polyethylene glycol,

talc and stearic acid (see columns 1, lines 9-15); (col. 3, lines 21-24); (col. 6, lines 1-7). The tablets have a hardness of 3 to 20 kg (Claim 1).

Suitable carbohydrates and sugars taught include sucrose, lactose, glucose and maltose. Sugar alcohols disclosed include sorbitol, mannitol, reduced malt syrup (maltitol), reduced starch saccharides, xylitol and the like (col. 5, lines 1-24) and Examples.

Additives taught include disintegrators, binders, acids, foaming agents, artificial sweeteners such as aspartame, flavorants, lubricants, colorants, etc. (col. 5, lines 55-67).

While Makino *et al.* do not teach all the instantly claimed amounts and/or ranges, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that Applicants have not demonstrated any unexpected or surprising results attributable to the claimed amounts. The prior art teaches a similar tablet formulation as claimed that is comprised of similar components used for the same field of endeavor as that of the Applicant's invention.

Given the explicit teachings of Makino *et al.*, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh
Primary Examiner
Art Unit 1615
January 19, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER
TC-1600

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